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December 30, 2014

**VIA ECF AND FEDEX**

The Honorable Mary L. Cooper  
United States District Judge  
Clarkson S. Fisher Building & U.S. Courthouse  
402 East State Street, Room 5000  
Trenton, New Jersey 08608

Re:   Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al.  
Civil Action No. 11-3962 (MLC)(DEA)

Dear Judge Cooper:

This firm, together with Paul Hastings LLP and Loeb & Loeb LLP, represents plaintiffs Helsinn Healthcare S.A. and Roche Palo Alto LLC (together, "Plaintiffs") in the above-captioned action.

We are pleased to inform the Court that Plaintiffs and defendant Sandoz Inc. ("Sandoz") have reached an amicable resolution of this matter. Therefore, enclosed for Your Honor's consideration is a Consent Judgment and Dismissal Order which, subject to Your Honor's approval, would dismiss Sandoz from this case. If the enclosed Consent Judgment and Dismissal Order meets with Your Honor's approval, we respectfully request that it be so Ordered and entered on the docket.

Thank you for Your Honor's kind attention to this matter.

Respectfully yours,



Charles M. Lizza

Enclosure

cc:   All Counsel (via e-mail)  
      Hon. Douglas E. Arpert, U.S.M.J.

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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

HELSINN HEALTHCARE S.A. and  
ROCHE PALO ALTO LLC,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, LTD.,  
*et al.*,

Defendants.

**Civil Action No. 11-3962 (MLC)(DEA)  
Civil Action No. 11-5579 (MLC)(DEA)  
Civil Action No. 13-5815 (MLC)(DEA)  
(Consolidated)**

**Hon. Mary L. Cooper, U.S.D.J.  
Hon. Douglas E. Arpert, U.S.M.J.**

(Filed Electronically)

**CONSENT JUDGMENT AND DISMISSAL ORDER**

This action for patent infringement (the "Litigation") has been brought by Plaintiffs Helsinn Healthcare S.A. and Roche Palo Alto LLC (collectively, "Helsinn") against Defendant Sandoz Inc. ("Sandoz") for infringement of United States Patent Nos. 7,947,724, 7,947,725, 7,960,424, 8,518,981, 8,598,218, and 8,598,219 (collectively, the "Helsinn Patents"). Helsinn's commencement of the Litigation was based on its receipt of notice from Sandoz that Sandoz had filed Abbreviated New Drug Application ("ANDA") No. 202521 with the United States Food and Drug Administration ("FDA") containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) directed to the Helsinn Patents and seeking approval to market generic

versions of palonosetron hydrochloride injections (Eq. 0.075 mg base/1.5 mL (Eq. 0.05 mg base/mL) and Eq. 0.25 mg base/5 mL (Eq. 0.05 mg base/mL)).

Helsinn and Sandoz have agreed to enter into a good-faith final settlement and license agreement regarding this Litigation on the expectation and belief that this would eliminate the substantial litigation costs that would otherwise be incurred by both Helsinn and Sandoz during the Litigation, while also serving the public interest by saving judicial resources and avoiding the risks to each of the parties associated with infringement. This reasonable final settlement will afford Helsinn and Sandoz the procompetitive opportunity to more productively use money and other resources that would have been spent in the continued prosecution and defense of this Litigation, to the benefit of the parties and consumers alike, such as by investing more money in pharmaceutical research and development.

Each of Helsinn and Sandoz acknowledge there is significant risk to each of them associated with the continued prosecution of this Litigation and have consented to entry of this Consent Judgment and Dismissal Order through a final settlement as reflected herein. The Court, upon the consent and request of Helsinn and Sandoz, hereby acknowledges the following Consent Judgment and, upon due consideration, issues the following Dismissal Order.

Helsinn and Sandoz now consent to this Consent Judgment and Dismissal Order and

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that:

1. Subject matter jurisdiction, personal jurisdiction, and venue solely with respect to the Litigation are all proper in this Court.
2. In this Litigation, Helsinn has charged Sandoz with infringement of the Helsinn Patents in connection with Sandoz's submission of ANDA No. 202521 directed to palonosetron

hydrochloride injections (Eq. 0.075 mg base/1.5 mL (Eq. 0.05 mg base/mL) and Eq. 0.25 mg base/5 mL (Eq. 0.05 mg base/mL)) to the FDA.

3. In response to Helsinn's charges of patent infringement, Sandoz has alleged certain defenses and counterclaims. No decision has been obtained by the parties from this Court regarding these charges of infringement or these defenses and counterclaims.

4. Sandoz has not rebutted the statutory presumption that the Helsinn Patents are valid and enforceable in the Litigation. This admission is without prejudice to Sandoz's defenses and counterclaims that the Helsinn Patents are invalid.

5. Sandoz admits that the submission of ANDA No. 202521 containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of generic palonosetron hydrochloride injections (Eq. 0.075 mg base/1.5 mL (Eq. 0.05 mg base/mL) and Eq. 0.25 mg base/5 mL (Eq. 0.05 mg base/mL)) within the United States before the expiration of the Helsinn Patents was a technical act of infringement of the Helsinn Patents under 35 U.S.C. § 271(e)(2)(A). This admission is without prejudice to Sandoz's defenses and counterclaims that the Helsinn Patents are invalid.

6. All claims, counterclaims, and affirmative defenses presented by Helsinn as between it and Sandoz, or by Sandoz, in the Litigation are hereby dismissed without prejudice.

7. Sandoz, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them shall not engage in manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any generic palonosetron hydrochloride injections (Eq. 0.075 mg base/1.5 mL (Eq. 0.05 mg base/mL) and/or

Eq. 0.25 mg base/5 mL (Eq. 0.05 mg base/mL)) that are the subject of ANDA No. 202521 except as permitted by the Settlement and License Agreement that the Parties have entered into.

8. Helsinn and Sandoz each expressly waives any right to appeal from this Consent Judgment and Dismissal Order.

9. This Court retains jurisdiction over Helsinn and Sandoz for purposes of enforcing this Consent Judgment and Dismissal Order.

10. The Clerk of the Court is directed to enter this Consent Judgment and Dismissal Order forthwith.

**IT IS SO STIPULATED:**

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**SO ORDERED:**

This \_\_\_\_\_ day of \_\_\_\_\_, 2014

\_\_\_\_\_  
HONORABLE MARY L. COOPER  
UNITED STATES DISTRICT JUDGE